DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M3548N

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-38

March 6, 2000

FACILITY ID# 145854

Richard Gould
Director of Radiology
Watson Clinic - Diagnostic Breast Center
1600 Lakeland Hills Blvd.
Lakeland, Florida 33804

Dear Mr. Gould:

Your facility was inspected on February 23, 2000 by a representative of the State of Florida, on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standard for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

Mammograms were processed when the processor was out of limits, for at least six days.

Level 2

1. There are no written procedures for handling consumer complaints.

2. The medical physicist reports for the Lorad Medical System X-Ray unit 7 & 8 were incomplete because artifact evaluations were not conducted.

The specific deficiencies noted above appeared on the List of Observations which was issued to your facility on February 23, 2000. These deficiencies are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations.

If your facility is unable to complete the corrective actions within 15 working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Timothy J. Couzins, Compliance Officer, U. S. Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,

Marie A. Urban
Acting Director
Florida District

cc: Florida Department of Health, Bureau of Radiation Control